MAR 0 1 2007

B. 510(k) Summary of Safety and Effectiveness

Triage® Protein C Test

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K062840**

1. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	9975 Summers Ridge Road San Diego, CA 92121
Telephone:	(858) 805-2722
Telefax:	(858) 586-7543
Contact Person:	Fil V. Buenviaje Manager, Regulatory Compliance
Date Summary Prepared:	February 13, 2007

2. Device Name and Classification

Trade Name:	Triage® Protein C Controls and Triage® Protein C Calibration Verification Controls
Common Name:	Protein C Controls; Single (Specified) Analyte Controls (Assayed and Unassayed)
Classification of Device:	21 CFR 862.1660, Quality Control Material (Assayed and Unassayed) Product Code: JJX

3. Predicate Devices

Triage® BNP (B-Type Natriuretic Peptide) Controls (K000230)
PrognostiX CardioMPO™ Control Kit (K050029)

4. Device Description

The Triage Protein C Control 1 and Control 2, and the Triage Protein C Calibration Verification Control Levels A, B and C are single-use, 0.25 mL unit dose liquid external quality control materials prepared with concentrated purified Protein C in human citrated plasma at defined levels. The controls are stored frozen at < -20°C. The liquid external quality control materials are not calibrators and are not used to calibrate the Triage Protein C Test.

5. Intended Use

The Triage Protein C Controls are assayed materials to be used with the Triage Protein C Test to assist the laboratory in monitoring test performance.

The Triage Protein C Calibration Verification Controls may be used to validate the performance of the Triage Protein C Test throughout the measurable range of the assay.

6. Product Performance

The performance of the Controls were evaluated using a panel consisting of 240 coded samples. Testing was conducted in duplicate, twice per day over twenty working days at three different sites. Excellent agreement existed between the observed and expected values. No statistically significant differences were observed between sites on test precision.

7. Comparison to Predicate Device

The Triage Protein C Controls and Triage Protein C Calibration Verification Controls employ similar characteristics to predicate devices including single analyte assay control, 2 or 3 levels, liquid control, human plasma/serum matrix and ≤ -20°C storage condition.

8. Conclusion

The information presented in this Premarket Notification demonstrates the suitability of the device for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution. Further, the information presented herein indicate that the Triage Protein C Controls and Triage Protein C Calibration Verification Controls are substantially equivalent in intended use and performance to other previously cleared control materials, thereby supporting 510(k) clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

BIOSITE INCORPORATED
C/O Fil V. Buenviaje
9975 Summers Ridge Road
San Diego, California 92121

MAR 0 1 2007

Re: k062840
Trade/Device Name: Triage® Protein C Controls
Triage® Protein C Calibration Verification Controls
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GGN
Dated: September 20, 2006
Received: September 22, 2006

Dear Mr. Buenviaje:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062840

Device Name: **Triage® Protein C Controls and Triage® Protein C Calibration Verification Controls**

Indications for Use:

The Triage Protein C Controls are assayed materials to be used with the Triage Protein C Test to assist the laboratory in monitoring test performance.

The Triage Protein C Calibration Verification Controls may be used by the laboratory to validate the performance of the Triage Protein C Test throughout the measurable range of the assay.

Prescription Use X AND/OR Over-The Counter Use
(Per 21 CFR 801.109) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Page 1 of

510(k) K062840